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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/269,897	04/02/1999	KATSUMI AOYAGI	4047	1769

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EXAMINER
ZEMAN, ROBERT A

ART UNIT	PAPER NUMBER
1645	15

DATE MAILED: 07/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/269,897	Applicant(s) AOYAGI ET AL.	
	Examiner Robert A Zeman	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *08 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,9-12 and 31-41* is/are pending in the application.

4a) Of the above claim(s) *12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,9-11 and 31-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *4,9-12 and 31-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-11-2001 has been entered.

The amendment filed on 5-8-2002 has been entered. Claims 4, 9-11, 31-32 and 34-41 have been amended. Claims 13-30 have been cancelled. Claims 4, 9-12 and 31-41 are pending. Claim 12 remains withdrawn from consideration. Claims 4, 9-11 and 31-41 are currently under examination.

Claim Objections Withdrawn

The objection to claims 4-6 and 7-11 for failing to introduce each claim with the proper article is withdrawn in light of the amendment thereto and the cancellation of claims 5-6 and 7-8.

Claims Rejections Withdrawn

The rejection of claims 10, 36 and 40 under 35 USC § 112, second paragraph, for the improper use of the phrases "i.e. and e.g.," is withdrawn in light of the amendment thereto.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claim 4 under 35 USC § 112, second paragraph, being vague and indefinite for use of the phrase "contains urea, an imidazole ring-containing compound or an indole ring-containing compound" is maintained for reasons of record. Applicant has failed to address said rejection is his response.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 31 and 9-10 under 35 USC § 102(b) is maintained for reasons of record.

Applicant argues:

1. Applicant's, in contrast to Cummins et al., do not disclose the use of alchoholamines or cholic acid or its derivatives or salts.
2. Cummins et al. does not disclose the use of amphoteric surfactants or denaturants.
3. The anionic surfactant not only liberates the viral antigen but may also denature said antigen. Applicant believes that the non-ionic and amphoteric surfactants reduce or eliminate this denaturing effect.

4. Cummins et al. is limited in its application to Herpes simplex virus.

5. There is no way of knowing what the effect of the added ingredients of Cummins would have on the denaturing of the core antigens.

6. Methodology disclosed by Cummins et al. include repetitive treatment of the aforementioned additional ingredients

7. Claim 31 has been amended to recite amounts of the anionic and non-ionic surfactants.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to points 1-6, the instant claims are drawn to a method for treating a virus-containing sample **comprising** the steps of: 1) treating a sample with a treatment solution **containing** an anionic surfactant and either an amphoteric surfactant **or** a nonionic surfactant **or** a protein denaturant; 2) obtaining a treated sample that can be readily subjected to an immunoassay using a probe without affecting the probe. Since Cummins et al disclose of treating a virus containing sample using a composition comprising of an alcoholamine, **a non-ionic surfactant**, cholic acid and an **anionic surfactant** for the extraction of herpes simplex viral antigens (see columns 3-4), Cummins et al. clearly anticipates the aforementioned claims which recite an method for treating virus-containing samples with a solution containing an anionic surfactant and a non-ionic surfactant. Since the claims recite open claim language, the claimed composition is not limited to the components explicitly recited. Additionally, the theorized effect of various components is irrelevant since they rely on limitations not recited in the instant claims.

Finally, with regard to point 7, Cummins discloses that the concentration of the nonionic surfactant is at least 1 weight percent and the concentration of the anionic surfactant is at least 0.1 weight percent (see column 4, lines 14-17 and lines 29-32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 4, 9-11 and 31-41 under 35 U.S.C. 103(a) as being unpatentable over Sharma (WO 92/19285) in view of Kokai (Japanese Patent Abstract No. 53-104724, IDS-4) and Cloyd et al. (U.S. Patent No. 6,074,646) is maintained for reason of record.

Applicant argues:

1. Sharma is directed to the disinfection of blood products through the destruction of bacterial cells and viruses. The present invention is not.

2. Sharma does not teach a treatment solution comprising an anionic surfactant and an amphoteric surfactant and a nonionic surfactant or protein denaturant.

3. Sharma does not want core proteins preserved. The goal of his method is to kill everything in the blood sample.

4. The purpose of the Kokai reference is to prepare globular uniform particles of HbsAg by treating serum with a nonionic surfactant and a protein-denaturing agent such as urea or guanidine.

5. The purpose of the Kokai reference is different from that of the instant invention.

6. The Kokai reference does not disclose the use of a nonionic surfactant in combination with an anionic surfactant or an amphoteric surfactant.

7. Cloyd et al. disclose the same components as the instant invention, but they are used individually but do not teach the use of combinations of surfactants or the use of other materials such as denaturing agents.

8. Applicant believes that Cloyd et al teaches only the use of one nonionic surfactant.

9. Applicant contends that different uses and different classifications of the cited references are such that it would not be suggested to one of skill in the art to combine them for any purpose.

10. Neither the Kokai nor Cloyd reference provide any basis for combination with Sharma.

11. The negative teachings of Cloyd teach away form using this in the invention of Cloyd.

Applicant's arguments have been fully considered and have been deemed non-persuasive.

As outline previously in Paper No.9, Sharma discloses a composition and method of use for disinfecting blood and discloses that the method is useful for preparation of samples for laboratory testing. Said composition contains at least one non-ionic surfactant and a stabilizer. Sharma differs from the claimed invention in that he does not disclose the use of combination of surfactants (i.e. non-ionic, anionic and amphoteric). Kokai No. 53-104724 discloses the use of non-ionic surfactants and protein-denaturing agents (urea) for the removal of HBV antigens from blood samples (See 2nd paragraph). Cloyd et al. disclose the treating of HIV infected sera with a variety of amphoteric surfactants, non-ionic surfactants, anionic surfactants and protein denaturing agents (See column 19). Additionally Cloyd et al. disclose that the aforementioned agents inactivated the viral agents in the sample since they were non-reactive to HIV specific antibodies. This indicates that virus has been ruptured and that the envelope protein gp120 is not intact. Contrary to Applicant's assertion, it does not mean that the samples have been rendered unsuitable for use with a probe. Consequently, it would have been obvious to one of skill in the art to use the combinations of surfactants disclosed by Cloyd et al. and Kokai No. 53-104724 in the method disclosed by Sharma since the **combinations** of the various surfactants and protein denaturing agents would **enhance** the effectiveness of the Sharma's method of disinfecting samples for use in laboratory tests since their effects would be additive. Additionally, Kokai No 53-104727 disclose that the use of the disclosed reagents results a material that can be used as raw material for a vaccine and a standard antigen reagent. Consequently, all the limitations of the instant invention are encompassed by the combination of the cited references. Applicant is

reminded that the aforementioned rejection is based on the combination of **all** the cited references.

New Claim Objections

Claim 9 is objected to because of the following informalities: Said claim contains an obvious typographical error. The word "genomic" is inadvertently spelled "gnomic". Appropriate correction is required.

New Grounds of Rejection

35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 9-10, 31-36 and 38-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a sample containing HCV or HBV with a treatment solution to obtain a sample suitable for detection with an antibody (probe), does not reasonably provide enablement for a method for treating solutions containing **any** virus (other than HCV or HBV) with a treatment solution to obtain a sample suitable for detection with **all** probes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification effectively demonstrates that the claimed method is effective in releasing the core antigens of HCV and HBV. Said antigens were further demonstrated to bind

with anti-HCV and ant-HBV antibodies. The specification is very detailed in outlining the concentrations of the various components of the treatment solution that need to be used in order to effectively release the antigens from the intact virus while maintaining its immuno-structure. However, the specification is silent on what components and concentrations of said components, if any, would be needed to achieve the same results if another virus were being tested for. Additionally, the specification provides no guidance on the use of any probe other than antibodies, regardless of the virus being tested. Given that each probe type would require vastly different conditions and methodologies in order to function properly (i.e. the conditions for using a RNA probe would be vastly different than using a substrate probe), it would be impossible for one of skill in the art to predict which methodologies and treatment solutions, if any, would be effective. Consequently, the specification does not enable any person skilled in the art to make and use the invention commensurate in scope with the rejected claims.

Claims 4, 9-11, 31-32, 34-37 and 39-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 31 and 32 recite the limitations "**at least 0.5%** of an anionic surfactant" and "an amphoteric surfactant **at least 0.1% of**". Said limitations do not seem to be disclosed in the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 9-11 and 31-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10, 36 and 40 recite improper and confusing Markush language. Use of the term "including" and the use of many commas makes it impossible to determine the members of the Markush group.

Claims 31-33 are rendered vague and indefinite by the use of the phrase "can be readily subjected..." It is unclear whether being subjected to an immunoassay is a limitation of the instant claims since having the capacity to do something is different than actually doing it. As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 31 is rendered vague and indefinite by the use of the term "at least 0.1% of". It is unclear whether said term is referring to the concentration of the amphoteric surfactant or the nonionic surfactant.

Claims 31-32 are rendered vague and indefinite by the use of the terms "at least 0.5% of" and "at least 0.1% of". It is unclear on what basis said concentrations are based. Is it a percentage based on volume or some other measure? As written, it is impossible to determine the metes and bounds of the claimed invention.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A Zeman whose telephone number is (703) 308-7991. The examiner can normally be reached on M-Th 7:30 am - 5:00 pm and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner, can be reached on (703) 308-1032. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DONNA WORTMAN
PRIMARY EXAMINER

Robert A. Zeman
July 24, 2002